

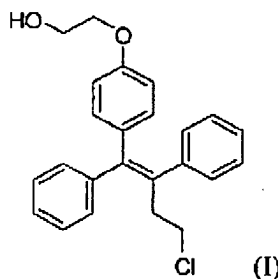
Appl. No. 10/783,024

Attorney Docket No. 13601-016

Amendment and Reply to Office Action of September 28, 2007

This listing of claims will replace all prior versions and listings of claims in the application:

1. **(Currently Amended)** A solid drug formulation comprising granulates containing a therapeutically active compound in particulate form said compound having of the formula (I)



or a geometric isomer, a stereoisomer, a pharmaceutically acceptable salt, an ester thereof or a metabolite thereof, wherein 90% of the particles have a size less than 50 micrometers and 50% of the particles have a size less than 15 micrometers, in combination with one or more intra-granular excipients, wherein at least 80% of the formulation is dissolved within 30 minutes after subjecting said formulation to dissolution testing at pH 9.8 according to the USP 24 paddle method.

2. **(Original)** The drug formulation according to claim 1 wherein compound (I) is ospemifene
3. **(Original)** The drug formulation according to claim 1 wherein at least one intra-granular excipient is a disintegrant.
4. **(Original)** The drug formulation according to claim 1 wherein at least one intra-granular excipient is a diluent.
5. **(Original)** The drug formulation according to claim 1 wherein at least one intra-granular excipient is a binder

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6. **(Original)** The drug formulation according to claim 1 wherein the intra-granular excipient is

- a combination of at least one diluent and at least one binder;
- a combination at least one diluent and at least one disintegrant ;
- a combination of at least one disintegrant and at least one binder; or
- a combination of at least one diluent, at least one disintegrant and at least one binder.

7. **(Original)** The drug formulation according to claim 3 wherein the disintegrant is selected from the group consisting of povidone, crospovidone, carboxymethylcellulose, methylcellulose, alginic acid, croscarmellose sodium, sodium starch glycolate, starch, formaldehyde-casein and combinations thereof.

8. **(Original)** The drug formulation according to claim 4 wherein the diluent is selected from the group consisting of maltose, maltodextrin, lactose, fructose, dextrin, microcrystalline cellulose, pregelatinized starch, sorbitol, sucrose, silicified microcrystalline cellulose, powdered cellulose, dextrans, mannitol, calcium phosphate and combinations thereof.

9. **(Original)** The drug formulation according to claim 5 wherein the binder is selected from a group consisting of acacia, dextrin, starch, povidone, carboxymethylcellulose, guar gum, glucose, hydroxypropyl methylcellulose, methylcellulose, polymethacrylates, maltodextrin, hydroxyethyl cellulose and combinations thereof.

10. **(Withdrawn)** The drug formulation according to claim 1 wherein the granulates are made by dry granulation.

11. **(Original)** The drug formulation according to claim 1 wherein the granulates are made by wet granulation.

12. **(Withdrawn)** The drug formulation according to claim 1 wherein the formulation is a capsule comprising the granulates encapsulated in a shell.

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13. **(Withdrawn)** The drug formulation according to claim 12 wherein the formulation comprises an extra-granular lubricant.

14. **(Withdrawn)** The drug formulation according to claim 13 wherein the lubricant is selected from the group consisting of calcium stearate, magnesium stearate, stearic acid, talc, a vegetable oil, poloxamer, a mineral oil, sodium lauryl sulphate, sodium stearyl fumarate, zinc stearate and combinations thereof.

15. **(Withdrawn)** The drug formulation according to claim 1, wherein the formulation is a tablet comprising the granulates in combination with one or more extra-granular excipient.

16. **(Withdrawn)** The drug formulation according to claim 15, wherein the extra-granular excipient is selected from the group consisting of one or more disintegrants, one or more diluents, one or more binders, one or more lubricants, and their combinations.

17. **(Withdrawn)** The drug formulation according to claim 16, where the extra-granular disintegrant is selected from the group consisting of povidone, crospovidone, carboxymethylcellulose, methylcellulose, alginic acid, croscarmellose sodium, sodium starch glycolate, starch, formaldehyde-casein and combinations thereof.

18. **(Withdrawn)** The drug formulation according to claim 16, where the extra-granular diluent is selected from the group consisting of maltose, maltodextrin, lactose, fructose, dextrin, microcrystalline cellulose, pregelatinized starch, sorbitol, sucrose, silicified microcrystalline cellulose, powdered cellulose, dextrates, mannitol, calcium phosphate and combinations thereof.

19. **(Withdrawn)** The drug formulation according to claim 16 wherein the extra-granular binder is selected from a group consisting of acacia, dextrin, starch, povidone, carboxymethylcellulose, guar gum, glucose, hydroxypropyl

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methylcellulose, methylcellulose, polymethacrylates, maltodextrin, hydroxyethyl cellulose and combinations thereof.

20. **(Withdrawn)** The drug formulation according to claim 16 wherein the extra-granular lubricant is selected from the group consisting of calcium stearate, magnesium stearate, stearic acid, talc, a vegetable oil, poloxamer, a mineral oil, sodium lauryl sulphate, sodium stearoyl fumarate, zinc stearate and combinations thereof.

Claims 21 – 23 **(Canceled)**

24. **(New)** The drug formulation according to claim 2 wherein at least one intra-granular excipient is a disintegrant.

25. **(New)** The drug formulation according to claim 2 wherein at least one intra-granular excipient is a diluent.

26. **(New)** The drug formulation according to claim 2 wherein at least one intra-granular excipient is a binder

27. **(New)** The drug formulation according to claim 2 wherein the intra-granular excipient is

- a combination of at least one diluent and at least one binder;
- a combination at least one diluent and at least one disintegrant ;
- a combination of at least one disintegrant and at least one binder; or
- a combination of at least one diluent, at least one disintegrant and at least one binder.

28. **(New)** The drug formulation according to claim 27 wherein the disintegrant is selected from the group consisting of povidone, croscopovidone, carboxymethylcellulose, methylcellulose, alginic acid, croscarmellose sodium, sodium starch glycolate, starch, formaldehyde-casein and combinations thereof.

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29. (New) The drug formulation according to claim 28 wherein the diluent is selected from the group consisting of maltose, maltodextrin, lactose, fructose, dextrin, microcrystalline cellulose, pregelatinized starch, sorbitol, sucrose, silicified microcrystalline cellulose, powdered cellulose, dextrans, mannitol, calcium phosphate and combinations thereof.

30. (New) The drug formulation according to claim 29 wherein the binder is selected from a group consisting of acacia, dextrin, starch, povidone, carboxymethylcellulose, guar gum, glucose, hydroxypropyl methylcellulose, methylcellulose, polymethacrylates, maltodextrin, hydroxyethyl cellulose and combinations thereof.